UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,339	01/11/2006	Ute Isele	H-33301A	9019

74479 7590 01/15/2010

Novartis Animal Health US Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
01/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,339	ISELE, UTE	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3*

10564339 - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *1-29,33-35 and 37-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/2006 and 7/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-63 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group II, claims 30-32, in the reply filed on October 20, 2009 is acknowledged.

Claims 1-29, 33-35, and 37-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 20, 2009.

Claims 1-63 are pending in the application. Claims 30-32 have been amended. Claims 30-32 will presently be examined to the extent they read on the elected subject matter of record.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed on January 11, 2006 and July 28, 2006 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over van Lengerich (US 6,500,463) in view of Kalbe et al. (CA 2,413,698).

Applicant's Invention

Applicant claims a method for the production of a highly palatable ductile chewable veterinary composition comprising i) feeding the hopper of an extruder with an effective amount of one or more ingredients that are active against animal pests; meat flavoring; partially gelatinized starch; a softener; and up to about 9% of water, ii) cooling constantly down the mixture of active ingredients and carriers so that the temperature of the extrudate that leaves the tip of the extruder does during the whole extrusion process at no time exceed 40° C, iii) pressing the extrudate through a die that is decisive for the shape of the chewable product, and iv) cutting the extrudate that leaves the extruder into equal pieces.

Determination of the scope of the content of the prior art (MPEP 2141.01)

van Lengerich teaches a process for producing discrete, particulate, shelf-stable encapsulated heat-sensitive components from solids, such as powders, or from solutions or dispersions of the component without the need for pre-drying of the solution or dispersion. van Lengerich teaches that the particulates may be produced at low temperatures without substantial heating or without substantial gelatinization of starch to avoid thermal destruction of the heat-sensitive components, and to avoid substantial expansion. An extrudable, formable, cuttable, mixture or dough may be obtained continuously without the need for removing or evaporating liquid plasticizer prior to

extrusion or forming. The processes of the present invention may be used for the continuous production of an edible composition for delivering pharmaceutically or nutritionally active components (col. 4, lines 44-64). van Lengerich teaches a solid encapsulant and/or a liquid encapsulant component which contains an active, sensitive encapsulant dissolved or dispersed in a liquid plasticizer is admixed with a plasticizable matrix material, which is plasticizable by the liquid plasticizer to encapsulate the active encapsulant at a low temperature and under low shear conditions. van Lengerich teaches a formable mixture is obtained without substantially gelatinizing or cooking the plasticizable matrix material or the substantially non-plasticizable matrix component (col. 7, lines 48-67). van Lengerich teaches the encapsulants and encapsulated products of the present invention may be edible such as pharmaceutically or biologically or nutritionally active components. van Lengerich teaches they may be used for human or animal consumption. The encapsulants and encapsulated products may be suspensions of microorganisms in water, pharmaceutically active compounds, vitamins or minerals in solid (col. 8, lines 50-65). van Lengerich further teaches the inclusion of a matrix component which is substantially non-plasticizable at room temperature, such as non-gelatinized starch, substantially non-gelatinized starch, an inert or bulky material, or carbohydrates which have a lower molecular weight than starches may disrupt, weaken, or soften the glassy matrix formed upon drying the formable mixture (col. 10, lines 14-20). van Lengerich teaches process compatible additional components to facilitate processing, or to improve sensory attributes such as taste, texture, or aroma may be employed, such as flavors (col. 13, lines 63-67).

van Lengerich teaches all of the ingredients may be admixed together at a temperature which does not substantially destroy the encapsulant or substantially gelatinize starch, such as temperatures of less than about 55° C., preferably less than 40° C., most preferably less than about 35° C (mixing ingredients, extrusion process does not exceed 40° C). Mixing or dough temperatures substantially higher than about 50° C are undesirable, because any fat or oil in the formula tends to separate, or the heat sensitive substances to be encapsulated and embedded would be destroyed. In embodiments of the invention, the temperature may be adjusted by external heating, below 50° C, preferably less than 40° C so as to facilitate forming and enable cutting without the material sticking to the cutter (col. 20, lines 4-22). van Lengerich teaches the resulting admixture can be compressed by extrusion through a die into a coherent, dough, capable of being cut into pellets or pieces (col. 20, lines 40-44). Van Lengerich teaches some or all of the dry ingredients may be preblended or dry blended and then admixed with any liquid components such as the plasticizer or a liquid encapsulant component (col. 21, lines 5-19) (pre-mixtures). van Lengerich teaches in example 4, col. 26, lines 64-67-col. 27, lines 1-13, an example of an encapsulated and protected enzyme, batch process. van Lengerich teaches a matrix blend consisting of 29 parts semolina, 6 parts wheat gluten, and 29 parts commercial, non-gelatinized wheat starch may be preblended and mixed with 11 parts of vegetable oil in a mixer for 3 minutes. Then 22 parts of liquid encapsulant (about 70% by weight water) comprising the enzyme phytase and subsequently 3 parts water may be added and mixed for 12 minutes to obtain a blend (mixing ingredients). The blend may then be extruded

through extrusion dies having a diameter of about 0.65 mm using a single screw extruder. The blend may be formed into a dough that can be extruded at about 90 bar and at a temperature of about 37° C (temperature not to exceed 40° C, pressing the extrudate through a die that is decisive for the shape). Upon exiting the die, the product may be cut with rotating knives into discrete particles of about 0.5 mm to about 1 mm in length and air dried for about 30 minutes to obtain shelf-stable pellets which contain encapsulated enzyme (cutting extrudate into equal pieces).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

van Lengerich does not teach the use of meat flavoring in the formulation. It is for this reason Kalbe et al. is added as a secondary reference.

Kalbe et al. teach starch-based extruded shaped articles, characterized in that they comprise specific aromas, bodying agents and pharmaceutical active compounds for animals (page 2, lines 25-27). Kalbe et al. teach the starch-based extruded shaped articles contain poultry liver aroma or meat aroma as aromas (page 2, lines 29-30). Harder et al. teach active compounds which are suitable are, in principle, all active compounds which are suitable for use in veterinary medicine. Especially suitable are the active compounds from the class of the depsipeptides, in particular cyclic depsipeptides. Kalbe et al. teach ancillary substances which are used are: starch, such as, starch from wheat, rice, maize, tapioca, rye, oats and potatoes (page 19, lines 13-14). Kalbe et al. teach materials which are especially suitable for shaping and bodying are cellulose and its derivatives (page 20, lines 1-2). Kalbe et al. teach materials which

act as humectants and plasticizers are water, glycerol, propylene glycol, polyethylene glycols and polypropylene glycols (page 20, lines 10-11). Kalbe et al. teach suitable aromas are powdered liver from cattle, poultry, sheep or pigs, preferably poultry and pigs, and other aroma preparations (page 21, lines 13-21). Kalbe et al. teach in example 2, 45% of cornstarch, 10% of sucrose, 10% of liver aroma, Haarmann & Reimer (meat flavoring), 10% of cellulose acetate powder, 1% of Aerosil and 4% of depsipeptide are homogenized and screened and the mixture is subsequently fed to an extruder via a measuring screw. Accordingly, 5% of water and 15% of glycerol (based on the total mixture) are pumped in via a metering pump. The extrusion temperature is 120° C. The extrudate formed is cut into pieces so that one piece contains the dose for 10 kg of the animal's bodyweight (page 22, lines 11-19).

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of van Lengerich and Kalbe et al. and use meat flavoring in the formulations. van Lengerich teaches a process of preparing pharmaceutical particulates, for humans and animals, at low temperatures without substantial heating or without substantial gelatinization of starch to avoid thermal destruction of the heat-sensitive components. van Lengerich teaches an extrudable mixture is obtained. One skilled in the art at the time the invention was made would have been motivated to use meat flavoring in the formulations because van Lengerich teaches compatible additional components to improve sensory attributes such as taste, texture, or aroma, such as flavors, may be employed in the formulations. As such, the

skilled artisan would have been motivated to use the meat flavorings and aromas as taught by Kalbe in the formulations because Kalbe teaches extrudable veterinary formulations with meat flavoring/aromas that are accepted readily by animals. In addition, it is known in the art to use meat flavorings to cover the taste of active agents in veterinary formulations to make the formulations more palatable to the animals.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616